

**In the Figures:**

Figures 1 – 4 have been amended to provide a unit of time for the horizontal axis. Redlines showing the amendment have been provided herewith.

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**In the specification:**

Page 1, line 20 to page 2, line 7:

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PH  
The increase in blood sugar levels resulting from the ingestion of carbohydrate foods has long been known; in fact it is of ongoing concern in those afflicted with diabetes mellitus. Furthermore, carbohydrate intolerance is one of the major criteria for a diagnosis of diabetes mellitus. The Oral Glucose Tolerance test employs ingested carbohydrate in a predetermined form and amount to quantify a test subject's response to a resulting glucose challenge. See *Oral glucose tolerance test*, Complete Guide to Medical Tests, <http://www.healthgate.com/tests/tests/test240.shtml>. Criteria have been established to evaluate this response according to the type of diabetes to be diagnosed. In the case of gestational diabetes, a blood glucose level exceeding 180 mg/dL is indicative of an impaired insulin response and therefore suggestive of diabetes. See *Oral glucose tolerance test for gestational diabetes*, <http://www.medstudents.com/ginob/ginob4t1.htm>. In the case of Type 1 or Type 2 diabetes, a blood glucose level exceeding 200 mg/dL is indicative of an impaired insulin response. While the blood glucose excursion may fall back to normal over a period of time, the oral glucose tolerance test is concerned only with the peak blood level of glucose. It does not concern itself with the rate of change in glucose levels or the amount of time it takes for glucose levels to fluctuate from a high point to a low point.

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Page 8, line 19 to page line 31:

AD

In order to provide a broad range of reference glucose values, a target glucose profile for each calibration visit was specified as a glucose level range of from less than 90 mg/dL through a targeted high of greater than 300mg/dL for each calibration visit, with a rate of change < 5 mg/dL/minute. As previously explained, it was necessary to obtain data sets in which the patterns resulting from the blood glucose reference values did not correlate across calibration visits; in other words, they were to be very dissimilar to each other. Therefore, the glycemic profiles were to be anti-correlated pairs; that is, one profile of a pair was to be the inverse of the other profile of the pair. During a first calibration visit, a glucose excursion that mimicked the first profile of a pair was to be achieved. The goal for a second visit was to achieve a glucose excursion that mimicked the second profile of the pair. Both calibration visits were eight hours in duration.

15 Page 9 - 10, Table 1:

AB

	<i>Sex</i>	<i>Diabetes Status</i>	<i>Year of Diagnosis</i>	<i>Health Status</i>	<i>Proteinuria</i>	<i>A1C</i>
1	F	2	1991	Good	1+	7.4
2	M	2	1994	Good	Neg	6.9
3	M	2	1993	Good	Neg	6.0
4	F	1	1982	Good	Neg	6.0
5	M	2	1998	Fair	Neg	6.1
6	M	2	1999	Good	1+	6.5
7	M	2	1996	Good	2+	5.5
8	F	1	1964	Good	Trace	7.5
9	F	2	1994	Good	Trace	7.5
10	F	2	1998	Good	Neg	5.3

Page 10, line 3 to line 10:

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The formula used to calculate the amount of carbohydrate required to produce the desired glucose excursion is:

$$CHO = \frac{TARGET - STARTING}{X}, \quad (1)$$

where *CHO* is the amount of carbohydrate in grams, 'Target' is the glucose concentration to be achieved, typically expressed either as mg/dL or mM, 'Starting' is the current glucose concentration, also expressed as mg/dL or mM, and *X* is a numerical index of the subject's sensitivity to carbohydrate challenge, described in greater detail below.

Page 10, line 12 to line 19:

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Table 2, below, shows a maximum and minimum, range and standard deviation of the glucose values for calibration visits of all clients. Maximum is the highest value achieved during a glucose excursion; minimum is a low value that may precede or follow a maximum value and the range is the span between maximum and minimum. As the results show, the target maximum (300mg/dL) and minimum values (90mg/dL) were achieved in ten out of twenty-three visits. Three subjects out of ten achieved the target range for both visits one and two.

Page 10 to Page 11, Table 2:

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Subject	Visit	Entire Day		Range	STD
		Max	Min		
1	1	287	103	184	68.0
1	2	228	57	171	48.0
2	1	313	66	247	87.0
2	2	379	76	303	97.1
3	1	326	62	264	90.9
3	2	297	71	226	68.2
4	1	399	40	359	103.7
4	2	372	64	308	95.1
5	1	283	70	213	49.1
5	2	326	75	251	88.1
6	1	234	97	137	42.7
6	2	345	102	243	82.9
7	1	331	44	287	99.3
7	2	230	58	172	49.8
7	3	287	97	190	60.2

8	1	395	74	321	98.3
8	2	357	74	283	88.2
8	3	390	54	336	99.0
9	1	255	103	152	36.3
9	2	217	75	142	56.7
9	3	196	70	126	40.0
10	1	173	67	106	36.8
10	2	207	85	122	36.7

Page 11, line 23 to page 12, line 9:

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- 5 The rate of change between the maximum glucose level and minimum glucose level was calculated for the first calibration visit (Table 2). This was calculated according to:

$$\text{Rate of change} = \frac{(\text{max glucose}) - (\text{min glucose})}{(\text{max time}) - (\text{min time})} \quad (2)$$

- 10 The rate of change is expressed as milligrams per deciliter (mg/dL) over minutes. The rate of change is an indicator of a subject's capacity for the movement in blood glucose necessary to achieve the targeted glucose profile. The targeted glucose profile's rate of change is  $\pm 1.33$  (mg/dL/minute. For calibration visit one, the rate is a negative value, since it describes a downward
- 15 trend. As Table 3, below, shows, three subjects (4, 5, and 6) had rates similar to that of the targeted profile.

Page 13, line 22 to line 11:

- A8<sup>20</sup>
- 'X' is a factor that serves as an index to carbohydrate sensitivity. The initial value is assigned by the clinician, according to type of diabetes and level of diabetes control, from a range of approximately 1 to 3, and is subsequently individualized to the subject. The amount of carbohydrate required to produce a target glucose
- 25 excursion is calculated using a starting, generalized value of X, assigned by the

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clinician, as previously described. The diabetic subject then ingests the calculated amount of carbohydrate. Blood glucose values are measured at regular intervals until the subject's blood glucose values reach a maximum. The actual maximum and the target maximum are compared and an individualized value of  $X$ ,  $X_i$  is calculated according to:

$$X_i = \frac{OBSERVED - STARTING}{CHO}, \quad (4)$$

where 'OBSERVED' represents the observed maximum, as contrasted with the target maximum. Thus, for an individual, assigned an initial  $X$  value of 2, who attained a maximum of 297mg/dL following ingestion of an amount of carbohydrate calculated to produce a maximum of 350mg/dl, the individualized value of  $X$ ,  $X_i$ , would be calculated as 1.7. This calculated value can be used by the subjects to further enhance their diabetes management. It can be assessed that the Type I clients (4 and 8) had a much higher sensitivity to carbohydrates (2.10 and 3.09, respectively) than the other clients. Table 4 below provides the sensitivity factors and Carbohydrate quantities employed for visit one profiles.

Page 14, line 16 to line 25:

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20 The calibration visits also provide an educational experience for the diabetic subjects. The test subjects indicate a greater awareness of the impact of carbohydrate foods on their blood glucose levels. Subjects who experience higher sensitivities in the morning may choose to move more of their carbohydrate food choices to the afternoon or evening, when their medication regimen may produce lower sensitivities. Furthermore, subjects report that their intake of carbohydrate is generally reduced, that they typically take smaller-sized portions of carbohydrate foods, and that nutritional information from food labels is more meaningful, all highly desirable outcomes in the management of diabetic conditions.